COMMONWEALTH OF VIRGINIA
Department of Environmental Quality
Piedmont Regional Office

STATEMENT OF LEGAL AND FACTUAL BASIS

permittee name – Sterilization Services of Virginia, Inc.
facility location -Henrico County, Virginia
Permit No. PRO51000

Title V of the 1990 Clean Air Act Amendments required each state to develop a permit program to ensure that certain facilities have federal Air Pollution Operating Permits, called Title V Operating Permits. As required by 40 CFR Part 70 and 9 VAC 5 Chapter 80, Sterilization Services of Virginia, Inc. has applied for a Title V Operating Permit for its Sterilization Services of Virginia facility in Henrico County. The Department has reviewed the application and has prepared a Title V Operating Permit.

Engineer/Permit Contact:_____ Date:_____

Air Permit Manager:_____ Date:_____

Regional Deputy Director:_____ Date:_____

FACILITY INFORMATION

Permittee
Sterilization Services of Virginia, Inc.
350 Barklay Blvd
Lincolnshire, IL 60069

Facility
Sterilization Services of Virginia
5674 Eastport Blvd
Henrico County, VA

AIRS ID No. 51-087-0159

SOURCE DESCRIPTION

SIC Code: 7389 – Business Services, Not Elsewhere Classified

Establishments primarily engaged in furnishing business services, not elsewhere classified, on a commission or fee basis:

Product sterilization service

Sterilization Service of Virginia sterilizes surgical instruments and medical products by the use of four ethylene oxide sterilizers which are controlled by a packed tower scrubber along with the use of seven aeration rooms all of which are controlled by a catalytic oxidizer.

The facility is a Title V major source of HAPs (i.e. Ethylene Oxide) and is subject to MACT O (40 CFR 63, Subpart O, Ethylene Oxide Emissions Standard for Sterilization Facilities) as a source using 10 tons or more of ethylene oxide in any consecutive 12-month period. This source is located in an attainment area for all criteria pollutants; however, the source is located in a VOC control area for VOCs. The facility was previously permitted under a Minor NSR Permit as listed in the Title V permit and this Statement of Basis.

COMPLIANCE STATUS

The facility is inspected once a year. The last inspection was performed on September 10, 2002 for this facility and the source was determined to be in full compliance.

EMISSIONS INVENTORY

The source did not mark the following statement on page 12 of the submitted Title V permit application:

"I have reviewed my Calendar Year 1996 emissions update, and I find that it properly accounts for all emission units except those specified below. The figures which would otherwise appear on this page are shown in the emissions update specified."

Nor the following statement on page 12 of the submitted Title V permit application:

"The above-referenced emissions data do not agree entirely in regard to unit reference numbers vs. the numbers shown on this form. A list is attached which explains the discrepancies."

However, attached is page 12 of the Title V permit application which was filled out by the applicant. In addition, the current calendar year (2001) emissions update is attached.
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Applicable Requirements

Emission Unit Applicable Requirements and control device identification:

Each of the units listed in the significant emissions units table **(under section II of the Title V permit)** as listed below are regulated in each of the NSR permits as noted in the following table. The listing of applicable requirements follows this table:

Emission Unit ID	Stack ID	Emission Unit Description	Size/Rated Capacity	Pollution Control Device Description (PCD)	PCD ID	Pollutant Controlled	Applicable Permit Date
1S1	E1	Vacudyne Contact Medical Products Ethylene Oxide Sterilizer # J90-12	Size (1S1): 4,938 cubic feet	Croll-Reynolds packed tower ethyl glycol scrubber	E1	VOC (Ethylene Oxide)	4/9/03
2S1	E1	Vacudyne Contact Medical Products Ethylene Oxide Sterilizer # J90-97	Size (2S1): 2,469 cubic feet	Croll-Reynolds packed tower ethyl glycol scrubber	E1	VOC (Ethylene Oxide)	4/9/03
3S1	E1	Vacudyne Contact Medical Products Ethylene Oxide Sterilizer # J90-98	Size (3S1): 1,708 cubic feet	Croll-Reynolds packed tower ethyl glycol scrubber	E1	VOC (Ethylene Oxide)	4/9/03
4S1	E1	Vacudyne Contact Medical Products Ethylene Oxide Sterilizer	Size (4S1): 1,575 cubic feet	Croll-Reynolds packed tower ethyl glycol scrubber	E1	VOC (Ethylene Oxide)	4/9/03
1 - 7 AE	E2	(7) Ethylene oxide aeration rooms for sealed surgical kits and other medical kits	Capacity: 1,210.7 lbs/hr of Ethylene Oxide (ETO) input	Vacudyne Catalytic Oxidizer	E2	VOC (Ethylene Oxide)	4/9/03
CEVs	FUG.	Chamber exhaust vents		NA	NA	VOC (Ethylene Oxide)	4/9/03

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Permit Dated April 9, 2003- The applicable requirements from the permit conditions are listed below along with inclusion of two additional periodic monitoring conditions and two additional recordkeeping conditions.

Control Technology Requirements:

1. **Emission Controls and Control Efficiency -** Ethylene oxide emissions from each of the sterilization chamber vents (emission unit ID #s: 1-7 AE) shall be controlled by a packed tower scrubber with a control efficiency of 99%. The scrubber and sterilizers shall be provided with adequate access for inspection.

   (9 VAC 5-80-110, Condition 4 of the April 9, 2003 permit and 40 CFR 63, Subpart O, Section 63.362)

2. **Emission Controls and Control Efficiency -** Ethylene oxide emissions from each aeration room vent (emission units: 1-7 AE) shall be controlled by a catalytic oxidizer with a control efficiency of 99%. The catalytic oxidizer shall be provided with adequate access for inspection.

   (9 VAC 5-80-110, Condition 5 of the April 9, 2003 permit and 40 CFR 63, Subpart O, Section 63.362)

3. The number of nitrogen washes and/or vacuum flushes of the sterilization chamber (emission unit ID #: 1S1 – 4S1) shall be in accordance with product requirements.

   (9 VAC 5-80-110, and Condition 6 of the April 9, 2003 permit)

4. The four sterilization chambers and the seven aeration rooms (emission unit ID #s: 1S1 – 4S1 and 1-7 AE) shall be designed so that they shall not individually nor collectively operate without the control equipment being on line.

   (9 VAC 5-80-110, and Condition 7 of the April 9, 2003 permit)

5. No more than two sterilizing chamber vents (emission unit ID #s: 1S1 – 4S1) shall exhaust emissions to the scrubber at any one time.

   (9 VAC 5-80-110 and Condition 8 of the April 9, 2003 permit)

6. The exhaust stacks (emission unit ID #s: 1S1 – 4S1 and 1 – 7 AE) shall be constructed to minimum heights as specified below:

Scrubber exhaust stack	45 feet
Oxidizer exhaust stack	45 feet

   (9 VAC 5-80-110 and Condition 19 of the April 9, 2003 permit)

B. Emission Estimates and Requirements

1. **Requirements by Reference -** This facility shall operate in conformance with 40 CFR 63, Subpart O, Ethylene Oxide Emissions Standard for Sterilization Facilities (MACT Standard).
(9 VAC 5-80-110 and Condition 3 of April 9, 2003 Permit)

2. Emissions from the scrubber exhaust (emission unit ID #s: 1S1 – 4S1) shall not exceed the limitations specified below:

Volatile Organic Compounds (Ethylene Oxide)	11.60 lb/hr	3.44 tons/yr*

*****Annual emissions shall be determined by the monthly usage of ethylene oxide calculated as the sum of each consecutive 12 month period.

(9 VAC 5-80-110 and Condition 20 of the April 9, 2003 permit)

3. Emissions from the oxidizer exhaust (emission unit ID #s: 1 – 7 AE) shall not exceed the limitations specified below:

Volatile Organic Compounds (Ethylene Oxide)	0.36 lb/hr	0.11 tons/yr*

*Annual emissions shall be determined by the monthly usage of ethylene oxide calculated as the sum of each consecutive 12 month period.

(9 VAC 5-80-110 and Condition 21 of the April 9, 2003 permit)

4. Emissions from the chamber exhaust vents (emission unit ID #: CEVs) shall not exceed the limitations specified below:

Volatile Organic Compounds (Ethylene Oxide)	14.53 lb/hr	4.31 tons/yr*

*Annual emissions shall be determined by the monthly usage of ethylene oxide calculated as the sum of each consecutive 12 month period.

(9 VAC 5-50-260 and Condition 22 of the April 9, 2003 permit)

5. Visible emissions from each of the exhaust stacks (emission unit ID #s: 1S1 – 4S1 and 1 – 7 AE) shall not exceed zero percent opacity.
(9 VAC 5-80-110 and Condition 23 of the April 9, 2003 permit)

C. Monitoring Requirements and Recordkeeping

1. The recirculation tank shall be equipped with a liquid level indicator to measure the scrubber liquor tank level (emission unit ID #s: 1S1 – 4S1). The liquid level indicator shall be maintained so that it is in proper working order at all times.
(9 VAC 5-80-110, Condition 9 of the April 9, 2003 permit and 40 CFR 63.364(b)(2))

2. The scrubber liquor level (emission unit ID #s: 1S1 – 4S1) in the recirculation tank shall be measured and recorded at least once per week. Monitoring is required during a week only if the scrubber unit has been operated. A low-flow alarm shall be installed to ensure adequate water flow to the scrubber. The low-flow alarm shall be maintained by the permittee such that it is in proper working order at all times. An annual internal inspection shall be conducted on the scrubber packing.
(9 VAC 5-80-110, Condition 10 of the April 9, 2003 permit and 40 CFR 63.364(b)(2))

3. The volume of any liquids added to the scrubber system (emission unit ID #s: 1S1 – 4S1) shall be recorded.
(9 VAC 5-80-110 and Condition 11 of the April 9, 2003 permit)

4. The operating limit for the packed tower scrubber (emission unit ID #s: 1S1 – 4S1) shall not exceed the maximum liquor (recirculation) tank level of 8 feet 3 inches.
(9 VAC 5-80-110, Condition 12 of the April 9, 2003 permit and 40 CFR 63.363(b)(2)(ii))

5. The permittee shall install, calibrate, operate, and maintain a temperature monitor accurate to $\pm 10^{o}$F (5.6^{o}C) at the outlet to the catalyst bed (emission unit ID #: 1 – 7 AE). The accuracy of the temperature monitor shall be verified twice each calendar year with a reference temperature monitor traceable to National Institute of Standards and Technology standards or an independent temperature measurement device dedicated for this purpose. During accuracy checking, the probe of the reference device shall be at the same location as the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be

verified in a calibrated oven (traceable to NIST standards).
(9 VAC 5-80-110, Condition 13 of the April 9, 2003 permit and 40 CFR 63.364(c)(4))

6. A data acquisition system for the temperature monitor shall continuously monitor the oxidation temperature (emission unit ID #s: 1 – 7 AE) at the outlet to the catalyst bed. The outlet temperature shall be recorded on a continuous basis (from 15 minutes or shorter) and shall be retained on site for 5 years.
(9 VAC 5-80-110, Condition 14 of the April 9, 2003 permit and 40 CFR 63.364(c))

7. The operating limit consists of the recommended minimum oxidation temperature (emission unit ID #s: 1- 7 AE) provided by the oxidation unit manufacturer for an operating limit.
(9 VAC 5-80-110, Condition 15 of the April 9, 2003 permit and 40 CFR 63.363(b)(3))

8. The computerized interlock system for the sterilization chambers and the aeration rooms air system shall remain in place to ensure the control equipment is on line when the sterilization chambers and the aeration rooms (emission unit ID #s: 1S1-4S1 and 1-7 AE) are in use.
(9 VAC 5-80-110)

9. The computerized interlock system for the sterilizing chamber vents shall remain in place to ensure no more than two sterilizing chamber vents (emission unit ID #s: 1S1-4S1) are being exhausted at any one time to the scrubber.
(9 VAC 5-80-110)

10. The catalytic oxidizer (emission unit ID #: 1-7 AE) shall comply with the following work practice:

    (i) Every 5 years, beginning 5 years after the initial compliance test as per 40 CFR 63.363, replace the catalyst bed with new catalyst material.

    (9 VAC 5-80-110, Condition 16 of the April 9, 2003 permit and 40 CFR 63.363(b)(4))

11. The facility must demonstrate continuous compliance with each operating limit and work practice standard (emission unit ID#: 1S1-4S1 and 1-7 AE) required under 40 CFR §63.363 (compliance and performance provisions) (such as condition nos. IV.C.

4, 7, and 10), except during periods of startup, shutdown, and malfunction, according to the methods specified in 40 CFR § 63.364 (monitoring requirements) (such as condition nos. IV.C. 1, 2, 5, and 6).
(9 VAC 5-80-110, Condition 17 of the April 9, 2003 permit and 40 CFR 63.363(f))

12. The facility shall use no more than 718,330 lbs per year of volatile organic compounds (ethylene oxide) (emission unit ID #: 1S1 – 4S1, 1 – 7 AE and CEVs) calculated monthly for each consecutive 12 month period.
(9 VAC 5-80-110 and Condition 18 of the April 9, 2003 permit)

13. The emissions from exhaust stacks (emission unit ID#s: 1S1 - 4S1 and 1 – 7 AE) shall be observed visually at least once each calendar month for at least a brief time period during normal operations to determine if they have any visible emissions (does not include condensed water vapor/steam), unless a 40 CFR 60 Appendix A Method 9 visible emissions evaluation is performed on the emissions unit. Each emissions unit observed having any visible emissions shall be followed up with a 40 CFR 60 Appendix A Method 9 visible emissions evaluation unless the visible emission condition is corrected as expeditiously as possible and recorded, and the cause and corrective measures taken are recorded. If an emission point is not operated during the calendar month, then no visible emission observation needs to be performed and a negative declaration shall be entered in the record stating the emission unit was not in operation. Should emission point operation be limited or intermittent, and/or adverse conditions (e.g. weather or darkness) prevail during the limited or intermittent operating period, no visible emission observation needs to be performed and a negative declaration shall be entered in the record along with the date(s) of operation, the hours of operation of the emission unit and a notation indicating inclement weather.
(9 VAC 5-80-110)

14. The permittee shall maintain records of all emission data and operating parameters necessary to demonstrate compliance with this permit. The content of and format of such records shall be arranged with the Director, Piedmont Region. These records shall include, but are not limited to:

    a. Annual usage of volatile organic compounds (ethylene oxide), calculated monthly as the sum of each consecutive 12 month period.

    b. The volume of liquid removed from the scrubber system, calculated monthly as the sum of each consecutive 12 month period.

c. The volume of liquid added to the scrubber system, calculated monthly as the sum of each consecutive 12 month period.

d. The weekly liquid level in the scrubber supply tank.

e. The liquid level of the scrubber feed tank prior to the removal and after the addition of any liquid to the system.

f. Records shall be kept demonstrating the number of nitrogen washes and/or vacuum flushes per product type.

g. Temperature monitoring data for the catalytic oxidizer.

h. Calibration data for the temperature monitor.

i. Records to demonstrate compliance with the work practice outlined in condition IV.C. 10 for the catalytic oxidizer shall consist of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

j. Records for all sources which are subject to 40 CFR § 63.362 shall comply with the recordkeeping requirements in 40 CFR § 63.10(b) and (c), according to the applicability in Table 1 of 40 CFR § 63.360, and in section 40 CFR § 63.367(recordkeeping requirements).

k. Records shall be kept demonstrating the heights of the scrubber exhaust stack and the oxidizer exhaust stack.

These records shall be available for inspection by the DEQ and shall be current for the most recent five years.
(9 VAC 5-80-110, Condition 25 of the April 9, 2003 permit and 40 CFR 63.367(a)&(d))

D. Reporting

1. For all sources (emission unit ID #s: 1S1 – 4S1 and 1 – 7 AE) which are subject to the emission standards in 40 CFR § 63.362 (Standards) shall fulfill all reporting requirements in 40 CFR §§ 63.10(a), (d), (e), and (f) of subpart A of 40 CFR Part

63, according to the applicability in Table 1 of 40 CFR § 63.360. These reports will be made to the Administrator at the appropriate address identified in 40 CFR § 63.13 of subpart A of 40 CFR Part 63.
(9 VAC 5-80-110, Condition 26 of the April 9, 2003 permit and 40 CFR 63.366(a))

2. Content and submittal dates for deviations and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per 40 CFR § 63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate (40 CFR § 63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in 40 CFR § 63.10(c)(5) through (13), as applicable in Table 1 of 40 CFR § 63.360, and information from any calibration test in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.
(9 VAC 5-80-110, Condition 27 of the April 9, 2003 permit and 40 CFR 63.366(a)(3))

E. Testing

1. The permitted facility shall be constructed so as to allow for emissions testing at any time using appropriate methods. Test ports will be provided at the following locations:

   Scrubber exhaust stack
   Oxidizer exhaust stack

   (9 VAC 5-80-110 and Condition 24 of the April 9, 2003 permit)

2. If testing is conducted in addition to the monitoring specified in this permit, the permittee shall use the following test methods in accordance with procedures approved by the DEQ as follows:

Pollutant	Test Method (40 CFR Part 60, Appendix A)
VOC	EPA Methods 18, 25, 25a
VOC	EPA Methods 24, 24a
Visible Emission	EPA Method 9

(9 VAC 5-80-110)

Periodic Monitoring for the four Vacudyne Contact Medical Products Ethylene Oxide Sterilizer (emission unit ID # 1S1 – 4S1) and seven Ethylene oxide aeration rooms for sealed surgical kits and other medical kits (Includes chamber vents) (emission unit ID# 1 - 7 AE).

The EPA periodic monitoring guidance, dated September 18, 1998, indicates on page 4 that periodic monitoring is required for each emission point at a source, subject to Title V of the Act, that is subject to an applicable requirement. The information listed below describes the periodic monitoring requirements for all of the applicable requirements for significant sources in the NSR permit issued on April 9, 2003. The requirements are generally contained in the permit issued on April 9, 2003 but some conditions have been developed to ensure that the periodic monitoring requirements of 9 VAC 5-80-110 E.2. have been met.

Condition 4 of the April 9, 2003 NSR permit (Condition IV.A.1. of the Title V permit):

> **Limitations: Emission Controls and Control Efficiency -** Ethylene oxide emissions from each of the sterilization chamber vents (emission unit ID #: 1S1- 4S1) shall be controlled by a packed tower scrubber with a control efficiency of 99%. The scrubber and sterilizers shall be provided with adequate access for inspection. **Parameter:** Ensuring there is a 99% emission reduction of ethylene oxide (VOC) as is required in the MACT O Emission Standard (under 40 CFR 63.362) when using an acid-water scrubber. **Monitoring and Recordkeeping:** Monitoring and recordkeeping will be as according to the monitoring and recordkeeping, for conditions IV.C. 1, 2, 3 and 4 in the Title V permit to ensure the scrubber is operating properly as follows:
>
> > (Condition 9* of the April 9, 2003 permit (Condition IV.C.1 of the Title V permit): The recirculation tank shall be equipped with a liquid level indicator to measure the scrubber liquor tank level (emission unit ID #s: 1S1 – 4S1). The liquid level indicator shall be maintained so that it is in proper working order at all times.

Condition 10* of the April 9, 2003 permit (Condition IV.C.2. of the Title V permit):
The scrubber liquor level (emission unit ID #s: 1S1 – 4S1) in the recirculation tank shall be measured and recorded at least once per week. Monitoring is required during a week only if the scrubber unit has been operated. A low-flow alarm shall be installed to ensure adequate water flow to the scrubber. The low-flow alarm shall be maintained by the permittee such that it is in proper working order at all times. An annual internal inspection shall be conducted on the scrubber packing.

** (Conditions 9 and 10 (Conditions IV.C.1.&2 of the Title V permit) are as per the MACT O monitoring requirements under 63.364(b)(2). The low flow alarm in condition no. 10 is not a MACT O requirement but is a good supplemental monitoring/safety to ensure the scrubber is working properly.)*

Condition 11** of the April 9, 2003 permit (Conditions IV.C.3. of the Title V permit):
The volume of any liquids added to the scrubber system (emission unit ID #s: 1S1 – 4S1) shall be recorded.

*** (This condition is not a MACT O condition. It was put in place to ensure the volume increases are the result of the ETO and sulfuric acid reaction (e.g. when monitoring the scrubber liquid tank level.)*

Condition 12*** of the April 9, 2003 permit (Condition IV.C.4. of the Title V permit):
The operating limit for the packed tower scrubber (emission unit ID #: 1S1 – 4S1) shall not exceed the maximum liquor (recirculation) tank level of 8 feet 3 inches.

**** (Condition 12* (Condition IV.C.4. of the Title V permit) *is as per the MACT O requirements established under 63.363(b)(2)(ii)). The maximum liquor level from the performance test was determined to be 8'3".)*

Additional recordkeeping shall be as according to conditions IV.C.14.b.,c.,d., and e in the Title V permit. **Reporting** shall be as according to conditions IV.D.1.&2. also in the Title V permit.

Condition 5 of the April 9, 2003 NSR permit (Condition IV.A.2. of the Title V permit):

Limitation: Ethylene oxide emissions from each aeration room vent (emission unit ID #: 1 – 7 AE) shall be controlled by a catalytic oxidizer with a control efficiency of 99%. The catalytic oxidizer shall be provided with adequate access for inspection.

Parameter: Ensuring there is a 99% emission reduction of ethylene oxide as is required in the MACT O Emission Standard (under 40 CFR 63.362) when using a catalytic oxidizer. **Monitoring and Recordkeeping:** Monitoring and recordkeeping will be as according to the monitoring and recordkeeping, for condition nos. 13, 14, and 15 of the April 9, 2003 NSR permit (Conditions IV.C. 5, 6 and 7 of the Title V permit) to ensure the scrubber is operating properly as follows:

Condition 13* of the April 9, 2003 permit (Condition IV.C.5 of the Title V permit): The permittee shall install, calibrate, operate, and maintain a temperature monitor accurate to $\pm 10^{o}$F (5.6^{o}C) at the outlet to the catalyst bed (emission unit ID #: 1-7 AE). The accuracy of the temperature monitor shall be verified twice each calendar year with a reference temperature monitor traceable to National Institute of Standards and Technology standards or an independent temperature measurement device dedicated for this purpose. During accuracy checking, the probe of the reference device shall be at the same location as the temperature monitor being tested. As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(The temperature monitor accuracy requirement of condition 13 (Condition IV.C.5. of the Title V permit) is as per the MACT O Monitoring Requirements under 63.364(c)(4) and the accuracy check (e.g. NIST) is as per 63.364(c)(4).)*

Condition 14* of the April 9, 2003 permit (Condition IV.C.6. of the Title V permit):

A data acquisition system for the temperature monitor shall continuously monitor the oxidation temperature (emission unit ID #s: 1 – 7 AE) at the outlet to the catalyst bed. The outlet temperature shall be recorded on a continuous basis (from 15 minutes or shorter) and shall be retained on a site for 5 years

**[However, the MACT O (7-1-02 Edition) (63.364(c)) states the following:*

"Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the

temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature recording falls below the minimum temperature."

Condition 14 (Condition IV.C.6. of the Title V permit) could not be written as according to the July 1, 2002 edition of the MACT O based on a February 12, 2003 e-mail from Sterilization Services to the Department which states the following:

"The equipment that records the temperature for the Donaldson unit is incapable of performing a daily average. Also our backup recording system the Honeywell Trueline recorder is incapable of performing a daily average."

However condition 14 (Condition IV.C.6. of the Title V permit) was able to be revised to a more stringent condition based on the following information:

A letter dated November 16, 2000 from Jonathan Wallace of Sterilization Services to DEQ stated the following:

"Re: Alternate compliance monitoring of the outlet temperature of the Oxidizer for Sterilization Services of Virginia AIRS ID No.: 51-087-0159

We wish to perform continuous temperature monitoring of the outlet temperature for the Oxidizer to assure the minimum temperature requirements are met. We feel this approach is better suited for daily regulatory reviews at our facility, plus it is more stringent than the hourly averages and three hour block average, currently in the MACT standard."

The Department responded in a letter dated December 7, 2000 which stated the following:

"In response to your 11/16/2000 letter concerning the above referenced request, approval is granted for Sterilization Services to perform continuous monitoring of the catalytic oxidizer's outlet temperature in lieu of calculating an hourly/3-hour average. The outlet temperature is to be recorded on a continuous basis and made available to the Department upon request. Be advised that the temperature of the outlet must be at least 283^{o}F on a continuous basis to be in compliance with the permit.

Condition #15 and #16 of the 2/22/99 permit stipulates that the temperature be monitored and used to create an hourly/3-hour average for compliance demonstration purposes. It is recommended that Sterilization Services submit a request to the Department to amend the permit to reflect the actual monitoring scenario."

Based on monitoring and recordkeeping being more stringent then MACT O's requirements, it should meet the MACT definition of "minor change to monitoring" and "minor change to recordkeeping" as follows (40 CFR 63.90(a))

Minor change to Monitoring:
"(1) A modification to federally required monitoring that:

(i) Does not decrease the stringency of the compliance and enforcement measures for the relevant standard;
(ii) …."

Minor change to Recordkeeping has some similar language with a few differences but basically the same tone as for the "minor change to monitoring"

"(1) A modification to federally required recordkeeping or reporting that:

(i) Does not decrease the stringency of the compliance and enforcement measures for the relevant standards;
(ii) *…."]*

Condition 15 of the April 9, 2003 permit (Condition IV.C.7 of the Title V permit): The operating limit consists of the recommended minimum oxidation temperature (emission unit ID #: 1- 7 AE) provided by the oxidation unit manufacturer for an operating limit.

Condition 16 of the April 9, 2003 permit (Condition IV.C.10 of the Title V permit):

The catalytic oxidizer shall comply with the following work practice:

(i) Every 5 years, beginning 5 years after the initial compliance test as per 40 CFR 63.363, replace the catalyst bed with new catalyst material.

(The recommended minimum oxidation temperature is as per the MACT O Compliance and Performance Testing Requirements under 63.363(b)(3).)

The combination of all four of the above conditions will ensure the emissions are reduced to the required emissions level of 99% for the MACT O and the State's applicable requirements.

Additional recordkeeping will be as according to condition no. IV.C.14.g., h.., i. and j.
Reporting shall be as according to condition no. IV.D.1.&2.

Condition 6 of the April 9, 2003 NSR permit (Condition IV.A.3 of the Title V permit):

Limitation: The number of nitrogen washes and/or vacuum flushes of the sterilization chamber (emission unit ID #: 1S1 – 4S1) shall be in accordance with product requirements. **Parameter:** Determine if the number of washes and flushes are as per the product requirements. The insurance of this parameter establishes more of the ETO is flushed out during the initial air/nitrogen washes which are controlled**. Monitoring and Recordkeeping:** Monitoring and recordkeeping will be as according to the following Title V recordkeeping condition IV C.14(f):

(f) Records shall be kept demonstrating the number of nitrogen washes and/or vacuum flushes per product type.

Condition 7 of the April 9, 2003 NSR permit (Condition IV.A.4 of the Title V permit):

Limitation: The four sterilization chambers and the seven aeration rooms (emission unit ID #s: 1S1 – 4S1 and 1-7 AE) shall be designed so that they shall not individually nor collectively operate without the control equipment being on line. **Parameter:** Determine if all of the sterilization chambers and the aeration rooms are operating with a control equipment being on line. **Monitoring:** Monitoring will be as according to the following Title V permit condition IV.C.8:

Monitoring Devices - The computerized interlock system for the sterilization chambers and the aeration rooms air system shall remain in place to ensure the control equipment is on line when the sterilization chambers and the aeration rooms (emission unit ID #s: 1S-4S1 and 1-7 AE) are in use.

Condition 8 of the April 9, 2003 NSR permit (Condition IV.A.5 of the Title V permit):

Limitation: No more than two sterilizing chamber vents (emission unit ID #s: 1S1 – 4S1) shall

exhaust emissions to the scrubber at any one time. **Parameter:** Ensure no more than two sterilizing chamber vents are being used at any one time to exhaust emissions to the scrubber. **Monitoring:** Monitoring will be as according to the following Title V permit condition IV.C.9:

The computerized interlock system for the sterilizing chamber vents shall remain in place to ensure no more than two sterilizing chamber vents (emission unit ID #s: 1S1-4S1) are being exhausted at any one time to the scrubber.

Condition 17 of the April 9, 2003 NSR permit (Condition IV.C.11 of the Title V permit): **Limitation:** The facility must demonstrate continuous compliance with each operating limit and work practice standard (emission unit ID #s: 1S1 – 4S1 and 1-7 AE) required under 40 CFR § 63.363 (compliance and performance provisions) (such as condition nos. IV C.4, 7, and 10), except during periods of startup, shutdown, and malfunction, according to the methods specified in 40 CFR § 63.364 (monitoring requirements) (such as condition nos. IV C. 1, 2, 5, and 6). **Parameter:** To ensure each operating limit and work practice standard is continuing to be performed. **Monitoring and Recordkeeping:** Monitoring and Recordkeeping will be as according to conditions IV.C.1., 2., 5., 6, 14.d., 14.g., 14.h. and 14i. in the Title V permit.

Condition 19 of the April 9, 2003 NSR permit (Condition IV.A.6 of the Title V permit):

Limitation: The exhaust stacks (emission unit ID #s: 1S1 – 4S1 and 1 – 7 AE) shall be constructed to minimum heights as specified below:

Scrubber exhaust stack	45 feet
Oxidizer exhaust stack	45 feet

Parameter: Ensure the stack heights are not any lower than the required 45 feet. **Monitoring and Recordkeeping:** Monitoring and recordkeeping will be as according to the following Title V Permit Condition IV.C.14.k.:

Records shall be kept demonstrating the heights of the scrubber exhaust stack and the oxidizer exhaust stack.

Conditions 20, 21 and 22 (respectively) of the April 9, 2003 NSR permit (Condition IV.B.2., 3 and 4 of the Title V permit):

Limitation: Emissions from the scrubber exhaust (emission unit ID #s: 1S1 – 4S1) shall not exceed the limitations specified below:

Volatile Organic Compounds (Ethylene Oxide)	11.60 lb/hr	3.44 tons/yr*

*Annual emissions shall be determined by the monthly usage of ethylene oxide calculated as the sum of each consecutive 12 month period.

Emissions from the oxidizer exhaust (emission unit ID #s: 1 – 7 AE) shall not exceed the limitations specified below:

Volatile Organic Compounds (Ethylene Oxide)	0.36 lb/hr	0.11 tons/yr*

*Annual emissions shall be determined by the monthly usage of ethylene oxide calculated as the sum of each consecutive 12 month period.

Emissions from the chamber exhaust vents shall not exceed the limitations specified below:

Volatile Organic Compounds (Ethylene Oxide)	14.53 lb/hr	4.31 tons/yr*

*Annual emissions shall be determined by the monthly usage of ethylene oxide calculated as the sum of each consecutive 12 month period.

Parameter: Ensure the emission limits are not being exceeded. **Monitoring and Recordkeeping:** Monitoring and recordkeeping of the annual emission limits established for the scrubber exhaust is based on the annual usage of volatile organic compounds (ethylene oxide) calculated monthly as the sum of each consecutive 12 month period of which is limited in terms of the annual volatile organic compounds (ethylene oxide) usage limit of the permit (in condition no. 18 of the April 9, 2003 NSR permit (Condition IV.C.12 of the Title V permit)). Therefore, as long as the usage is not exceeded the annual emission limits should not be violated.

(Note: The annual usage of volatile organic compounds (ethylene oxide) limit is for the annual emissions combined from the scrubber, the oxidizer and the chamber exhaust vents. Howvever, the total usage throughput is broken down into various percentages to calculate the annual emissions from these sources as per a letter from Griffith Micro Science (GMS) to Mr. David Markwordt of EPA in RTP, NC in regards to changing the MACT O to not require control of the chamber exhaust vents. The GMS letter proposed using 95.8% of ETO is released from the sterilizing chambers, 3% is then released from the aeration rooms and the remaining percentage which would be released would be from the chamber exhaust vents 1.2%. As a result, the following is an example of how the annual emissions were calculated (for the scrubber using the 95.8% release):

Annual Emissions of ETO from scrubber:

$$718{,}330\ \frac{lbs}{yr} \times \frac{95.8}{100} \times \frac{(100-99)}{100} \times \frac{1\ ton}{2{,}000\ lbs} = 3.44\ \frac{tons}{yr}$$

The hourly emissions for the scrubber, aeration rooms and the chamber exhaust vents were based on using the largest amount of gas concentration that can be placed in a sterilizer chamber at a pressure of 50 in of Hg and using the two largest volumes of the four sterilizer chambers. The reason only two chambers were used is based on only two chambers can be directed to the control equipment at any one time. (However, please note all chambers can be loaded with ETO, any remaining chambers which are not directed to the control equipment holds the ETO until the control equipment is available to receive the ETO.) As a result, the two largest chambers emissions were added together to derive the worst case hourly emissions of 1,210.7 lbs/hr of which was broken down into the various percentages of 95.8%, 3%, and 1.2%. An example of the calculated emissions is as follows (from the scrubber):

Hourly Emissions of ethylene oxide (ETO) from scrubber:

Chamber 1 (4,938 ft^3) = 807.1 lbs
Chamber 2 (2,169 ft^3) = 403.6 lbs
1,210.7 lbs/hr

$$1{,}210.7\ \frac{lbs}{hr} \times \frac{95.8}{100} \times \frac{100-99}{100} = 11.599\ \frac{lbs}{hr}$$

This information was provided in case a ratio would ever have to be performed between the scrubber, oxidizer and the chamber exhaust vents concerning the amount of emissions from the use of the total annual usage limit.

In addition, there was a discrepancy in the 6/98 Title V permit application which stated 0.431 tons of ETO/yr was being emitted from the oxidizer on page 12 of the application leading to a conclusion the NSR permit was being violated in regards to the emission limit for the oxidizer exhaust. It was determined the discrepancy was two fold. The first half of the discrepancy was the applicant inadvertently inserted the lbs/hr rather than the tons/yr and the second half of the discrepancy was due to half of the vacuum pump discharge emissions are no longer being ducted to the oxidizer but rather all of it is now ducted to the scrubber for safety reasons as per a December 23, 1998 letter from Jonathan Wallace of Sterilization Services to John Reinhardt of VADEQ.)

Recordkeeping demonstrating compliance with the annual throughput limits can be used to demonstrate compliance with the volatile organic compounds (ethylene oxide) annual emission limits; therefore, the throughput limits satisfy the periodic monitoring requirement for the emission limits and recordkeeping will be as according to the monitoring and recordkeeping, for Condition No. 25 a. of the April 9, 2003 NSR permit (Condition IV.C.14.a. of the Title V permit). In addition, if the maximum rated capacity is not exceeded then the short term limits of lbs/hr should not be exceeded.

Condition 22 of the April 9, 2003 NSR permit (Condition IV.B.4 of the Title V permit):

Limitation: Visible emissions from each of the exhaust stacks (emission unit ID #s: 1S1 – 4S1 and 1 – 7 AE) shall not exceed zero percent opacity. **Parameter:** Ensure opacity does not exceed zero percent. **Monitoring and Recordkeeping:** Monitoring and recordkeeping will be as according to the following Title V permit condition IV.C.13.:

The emissions from exhaust stacks (emission unit ID#s: 1S1 - 4S1 and 1 – 7 AE) shall be observed visually at least once each calendar month for at least a brief time period during normal operations to determine if they have any visible emissions (does not include condensed water vapor/steam), unless a 40 CFR 60 Appendix A Method 9 visible emissions evaluation is performed on the emissions unit. Each emissions unit observed having any visible emissions shall be followed up with a 40 CFR 60 Appendix A Method 9 visible emissions evaluation unless the visible emission condition is corrected as expeditiously as possible and recorded, and the cause and corrective measures taken are recorded. If an emission point is not operated during the calendar month, then no visible emission observation needs to be performed and a negative declaration shall be entered in the record stating the emission unit was not in operation. Should emission point operation be limited or intermittent, and/or adverse conditions (e.g. weather or darkness) prevail during the limited or intermittent operating period, no visible emission observation needs to be performed and a negative declaration shall be entered in the record along with the date(s) of operation, the hours of operation of the emission unit and a notation indicating inclement weather.

Obsolete conditions from NSR permits that can be removed

The Part 70 regulations (**Condition 30 of the April 9, 2003 permit**) define specific **inspection and entry requirements** consistent with the issuance of a TITLE V permit. These requirements are described in VII. general condition Q. of the Title V permit and are at least as stringent as the NSR requirements. Inclusion of these conditions would be redundant and the requirements have been overtaken by the Title V (Part 70) regulations.

Condition 28 of the April 9, 2003 permit is not being included as an applicable requirement in the Title V permit because it is redundant. The general applicable

requirement condition VII.T. describes the requirements for **transfer of ownership** relative to the Title V permit. The transfer of ownership requirements for the NSR permit are therefore inappropriate for inclusion in the Title V permit.

Condition 29 of the April 9, 2003 permit for modification or revocation for cause is not being included in the Title V permit as it is redundant since the Title V permit includes a "General Condition" in the permit for "Permit Revocation or Termination for Cause".

Condition 33 of the April 9, 2003 Permit which states the following:

"Annual requirements to fulfill legal obligations to maintain current stationary source emissions data will necessitate your prompt response to requests for information, to include, as appropriate: process and production data; changes in control equipment, and operating schedules. Such requests for information from the DEQ will either be in writing or by personal contact. The availability of information submitted to the DEQ or the Board will be governed by applicable provisions of the Freedom of Information Act, §§2.1-340 through 2.1-348 of the Code of Virginia, §10.1-1314 (addressing information provided to the Board), and 9 VAC 5-20-150 of the State Air Pollution Control Board Regulations. Information provided to federal officials is subject to appropriate federal law and regulations governing confidentiality of such information."

Condition 34 of the April 9, 2003 permit is not being included in the Title V permit as it is redundant since all of the applicable requirements from the NSR permit are included in the Title V permit. Therefore, it is not necessary to keep a copy of the NSR permit on the premises for Title V purposes.

Generally Applicable Requirements - Certain conditions within existing NSR permits may be applicable to all newly constructed or modified equipment that receive a permit. Below is a listing of these conditions:

1. In order to minimize the duration and frequency of excess emissions due to malfunctions of process equipment or air pollution control equipment, the permittee shall:

    a. Develop a maintenance schedule and maintain records of all scheduled and non-scheduled maintenance. These records shall be maintained on site for a period of five (5) years and shall be made available to DEQ personnel upon request.

b. Maintain an inventory of spare parts that are needed to minimize durations of air pollution control equipment breakdowns.

(9 VAC 5-20-110 and 9 VAC 5-50-20 E of State Regulations, Condition no. 31 of the NSR permit issued on April 9, 2003)

2. The permittee shall have available written operating procedures for the related air pollution control equipment. Operators shall be trained in the proper operation of all such equipment and shall be familiar with the written operating procedures. These procedures shall be based on the manufacturer's recommendations, at minimum. The permittee shall maintain records of training provided including names of trainees, date of training and nature of training.
(9 VAC 5-20-110 of State Regulations, Condition 32 of the NSR permit issued on April 9, 2003)

These conditions are being retained in the Title V permit because 1) they are applicable requirements generally applied to all modified and newly constructed equipment permitted through the minor NSR permit program; 2) they have an impact on the prevention of excess emissions and therefore are not environmentally insignificant; and 3) they require recordkeeping and reporting that may be included in periodic monitoring requirements.

Testing

A table of test methods has been included in the permit if testing is performed. The Department and EPA have authority to require testing not included in this permit if necessary to determine compliance with an emission limit or standard.

Streamlined Requirements - NA

GENERAL CONDITIONS

The permit contains general conditions required by 40 CFR Part 70 and 9 VAC 5-80-110, that apply to all Federal operating permit sources. These include requirements for submitting semi-annual monitoring reports and an annual compliance certification report. The permit also requires notification of deviations from permit requirements or any excess emissions, including those caused by upsets, within one business day.

STATE ONLY APPLICABLE REQUIREMENTS - NA

FUTURE APPLICABLE REQUIREMENTS - NA

INAPPLICABLE REQUIREMENTS - NA

INSIGNIFICANT EMISSION UNITS

The insignificant emission units are presumed to be in compliance with all requirements of the Clean Air Act as may apply. Based on this presumption, no monitoring, recordkeeping or reporting shall be required for these emission units in accordance with 9 VAC 5-80-110.

Insignificant emission units include the following:

Emission Unit No.	Emission Unit Description	Citation	Pollutant(s) Emitted (9 VAC 5-80-720 B)	Rated Capacity (9 VAC 5-80-720 C)
B1	Natural Gas Boiler	5-80-720C.2, a	NO_2, SO_2, VOC, CO, PM-10	2.5 MMBtu/hr
B2	Natural Gas Boiler	5-80-720 C.2,a	NO_2, SO_2, VOC, CO, PM-10	2.5 MMBtu/hr

[1]The citation criteria for insignificant activities are as follows:
9 VAC 5-80-720 A - Listed Insignificant Activity, Not Included in Permit Application
9 VAC 5-80-720 B - Insignificant due to emission levels
9 VAC 5-80-720 C - Insignificant due to size or production rate

CONFIDENTIAL INFORMATION

The permittee did not submit a request for confidentiality. All portions of the Title V application are suitable for public review.

PUBLIC PARTICIPATION

The proposed permit will be placed on public notice in the Richmond Times Dispatch from April 13, 2003 to May 12, 2003 (at close of business day).